DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Medical Device Submissions: Amending Premarket Regulations that Require Multiple Copies and Specify Paper Copies to be allowed in Electronic Format

Docket No. FDA-_2018-N-0628____

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule amends the existing premarket regulations requiring multiple copies and paper submissions to electronic format submissions without imposing any new requirements, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The proposed rule would amend device regulations requiring the number of copies firms must submit with a premarket pre-submission or submission. The proposed rule would also amend all device regulations containing a reference to the specific form of a submission to require an electronic submission. The amendment would produce cost savings for firms without imposing any additional regulatory burdens for submissions or affecting the Agency's ability to review submissions. Firms would incur minimal administrative costs to read and understand the rule. We expect the economic impact of this regulation to be a total net costs savings yielding positive net benefits.

Table 1 summarizes the benefits, costs, and distributional effects of the proposed rule, if finalized. We find that the proposed rule would result in annualized net benefits in the form of cost savings of around $2.80 million with a 3 percent discount rate and $2.71 million with a 7 percent discount rate.

Table 1. Summary of Benefits, Costs, and Distributional Effects of Proposed Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$3.37	$1.31	$5.47	2016	7%	10 years	Benefits are cost savings
		$3.37	$1.31	$5.47	2016	3%	10 years	Benefits are cost savings
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized $millions/year	$0.67	$0.67	$0.67	2016	7%	10 years	
		$0.57	$0.57	$0.57	2016	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/ To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: None Small Business: None Wages: None Growth: None							

Table 2 summarizes the Executive Order 13771 impacts of the proposed rule. Over an infinite time horizon, the present value of the total net costs would range from -$40.01 million to -$182.94 million at a 3 percent discount rate and from -$15.04 million to -$78.67 million at a 7 percent discount rate. Over an infinite time horizon, the total annualized net costs would range from -$1.17 million to -$5.33 million at a 3 percent discount rate, and range from -$0.98 million to -$5.15 million at a 7 percent discount rate. This proposed rule, if finalized, is considered an Executive Order 13771 deregulatory action.

Table 2. Summary of the Executive Order 13771 Impacts of the Proposed Rule over an Infinite Time Horizon (2016 $ millions)

	Primary Estimate (3%)	Lower Bound (3%)	Upper Bound (3%)	Primary Estimate (7%)	Lower Bound (7%)	Upper Bound (7%)
Present Value of Costs	$5.01	$5.01	$5.01	$5.01	$5.01	$5.01
Present Value of Cost Savings	$115.79	$45.02	$187.95	$51.55	$20.04	$83.68
Present Value of Net Costs	**($110.78)**	**($40.01)**	**($182.94)**	**($46.54)**	**($15.04)**	**($78.67)**
Annualized Costs	$0.15	$0.15	$0.15	$0.33	$0.33	$0.33
Annualized Cost Savings	$3.37	$1.31	$5.47	$3.37	$1.31	$5.47
Annualized Net Costs	**($3.23)**	**($1.17)**	**($5.33)**	**($3.04)**	**($0.98)**	**($5.15)**

Note: Values in parentheses denote net negative costs (i.e. cost-savings).

II. Preliminary Regulatory Impact Analysis

A. Baseline Conditions

An eCopy is an electronic version of a device-related submission on a CD, DVD, or flash drive. Under current regulation, FDA requires the submission of one paper copy and at least one eCopy for many types of premarket pre-submissions and submissions. In some cases, such as for original Premarket Approvals (PMAs), sponsors must include multiple eCopies in addition to the paper copy. Table 3 contains the number of paper copies and eCopies required by different types of submissions under current regulation (Ref. 1).

Table 3. Baseline Submission Requirements

Submission Type	Baseline Number of Full Paper Copies Required	Baseline Number of eCopies Required
Premarket Notifications (510(k)s)	1	1
Premarket Approvals (PMAs) and Humanitarian Device Exemptions (HDEs)		
Original	1	5
Panel-Track Supplements	1	5
180-Day Supplements	1	5
Real-Time Supplements	1	2
30-Day Notices	1	2
135-Day Supplements	1	2
Annual Reports	1	1
Post-Approval Study Reports	1	1

Modular PMAs/HDEs	1	2
Average Over All PMA/HDE Types	1	2.78
Investigational Device Exemptions	1	2

We estimate that FDA receives approximately 30,050 of these submissions each year. In Table 4, we summarize the number of annual submissions by type.

Table 4. Approximate Annual Number of Submissions by Submission Type

Submission Type	Annual Number of Submissions
510(k)s	10,000
PMAs (including supplements)	5,000
IDEs	15,000
Other	50
Total	**30,050**

B. Market Failure Requiring Federal Regulatory Action

Our current regulations have created an institutional failure by preventing industry and the Agency from adopting more efficient and less costly technologies to submit certain medical device applications. Given the ease of sharing and downloading a submission across multiple reviewers from a single eCopy, requiring multiple eCopies of each submission is unnecessary for FDA's reviewing purposes. Additionally, FDA submission reviewers typically use electronic versions of submissions rather than paper copies. Pre-market submissions are often thousands of pages long. The paper copy requirement therefore makes pre-market submissions unnecessarily costly for firms and somewhat burdensome for the Agency. This proposed rule would remove the institutional failure.

C. Purpose of the Proposed Rule

Under the proposed rule, FDA would eliminate the paper copy requirement for the types of submissions listed in Table 5. The proposed rule would also eliminate the paper copy requirement for related pre-submissions. Pre-market pre-submissions are requests from submission sponsors for feedback from FDA staff on their pre-market submissions. In lieu of a paper copy, firms would submit only a single copy in an electronic format. This copy may be an eCopy or an eSubmission, an electronic submission that is transmitted over the Internet instead of mailed to the Agency.

In Table 5, we summarize the new submission requirements under the proposed rule. The proposed rule would not amend regulations regarding submissions types for which submissions in electronic format are voluntary, including compassionate use Investigational Device Exemptions (IDEs), Emergency Use IDEs, Emergency Use Authorizations (EUAs), Device Master Files (MAFs), and Requests for Information (513(g)s). The rule would also not change the eCopy requirements for Biologics License Applications (BLAs) and Investigation New Drug Applications (INDs).

Table 5. New Submission Requirements Under the Proposed Rule

Submission Type	New Number of Full Paper Copies Required	New Number of Copies in Electronic Format Required
Premarket Notifications (510(k)s)	0	1
Premarket Approvals (PMAs) and Humanitarian Device Exemptions (HDEs)		
Original	0	1
Panel-Track Supplements	0	1
180-Day Supplements	0	1
Real-Time Supplements	0	1
30-Day Notices	0	1
135-Day Supplements	0	1
Annual Reports	0	1
Post-Approval Study Reports	0	1
Modular PMAs/HDEs	0	1
Average Over All PMA/HDE Types	0	1
Investigational Device Exemptions	0	1

D. Benefits of the Proposed Rule

The proposed rule would reduce the number of electronic copies required for many submission types, including Premarket Notifications (510(k)s) and Premarket Approvals (PMAs). Submissions in electronic format include eCopies, submissions copied to a CD, DVD, or flash drive and mailed to FDA, and eSubmissions, submissions transmitted over the Internet. The rule would therefore benefit firms by eliminating the costs of submitting redundant submissions in an electronic format.

The proposed rule would also eliminate the requirement that firms mail a full paper copy of their submission to the Agency. We expect that firms would instead only submit a paper copy of the submission's cover letter, an approximately 3-page document. Currently, firms must send multiple eCopies for many types of medical device pre-market pre-submissions and submissions. Eliminating the need to purchase, produce, and ship multiple eCopies would create small cost savings to firms without affecting the ability of the Agency to review submissions. The rule would benefit firms through printing and shipping costs savings, as submissions are often thousands of pages long.

1. Assumptions

Transmitting a copy of a medical device premarket pre-submission or submission over the Internet is less costly than mailing an eCopy, because it does not require the purchasing of CDs, DVDs, or flash drives and paying the mailing costs. Based on low adoption of the eSubmission program for 510(k) submissions, we expect that most sponsors would submit submissions as eCopies. For the purposes of this analysis, we conservatively assume that all firms mail eCopies of their medical device premarket submissions instead of transmitting eSubmissions over the Internet. To the extent that firms submit eSubmissions instead of

eCopies, our analysis underestimates the net benefits of the proposed rule. Given this assumption and the information in Tables 3 and 5, Table 6 shows our estimate of the reduction in the number of full paper copies and eCopies submitted for each submission type under the proposed rule.

Table 6. Change in Submission Requirements Under the Proposed Rule

Submission Type	Reduction in Number of Full Paper Copies Required	Reduction in Number of eCopies Required
Premarket Notifications (510(k)s)	1	0
Premarket Approvals (PMAs) and Humanitarian Device Exemptions (HDEs)		
Original	1	4
Panel-Track Supplements	1	4
180-Day Supplements	1	4
Real-Time Supplements	1	1
30-Day Notices	1	1
135-Day Supplements	1	1
Annual Reports	1	0
Post-Approval Study Reports	1	0
Modular PMAs/HDEs	1	1
Average Over All PMA/HDE Types	1	1.78
Investigational Device Exemptions	1	1

We conservatively assume that printing each type of submission covered by the proposed rule, including the paper required for all pre-submissions, requires an average of 2 reams of paper, or 1,000 pieces of paper. Under the proposed rule, we assume that firms would submit a 3-page paper copy of the submission's cover letter with the eCopy by priority mail using USPS or FedEx.

2. Printing Cost Savings

Table 7 shows our estimate of the printing cost savings of the proposed rule. The proposed rule would benefit applicants by eliminating the costs of printing a paper copy of the submission. The Agency receives approximately 30,050 submissions annually, and these submissions are, on average, 1,000 pages each. We assume that under the proposed rule, firms would only submit an eCopy on CD, DVD, or flash drive and a 3-page paper copy of the cover letter. Therefore, the average annual reduction in the number of pages printed for submission to FDA will be 29,959,850 pages.

A piece of paper costs between $0.01 and $0.04 per page, with a primary estimate of $0.03 per page. The cost of printing a single page on a mono printer, which prints in black and white only, ranges from $0.02 to $0.11, with a primary estimate of $0.06 on average (Ref. 2, adjusted to 2016 dollars).

The total annual printing cost savings equals the total cost of printing per page times the annual reduction in the number of pages printed under the proposed rule. The printing cost savings from the proposed rule would range from $0.94 million to $4.40 million annually, with a primary estimate of $2.67 million annually.

Table 7. Annual Printing Cost Savings of the Proposed Rule

Value	Low Estimate	Primary Estimate	High Estimate	Source
(1) Total Annual Submission	30,050	30,050	30,050	Table 4
(2) Baseline Pages per Submission	1,000	1,000	1,000	Assumption
(3) New Pages per Submission	3	3	3	Assumption
(4) Reduction in Pages per Submission	997	997	997	Row 2 - Row 3
(5) Total Annual Reduction in Pages Submitted	29,959,850	29,959,850	29,959,850	Row 1 * Row 4
(6) Cost of Paper per Page	$0.01	$0.03	$0.04	Assumption
(7) Cost of Mono Printing per Page	$0.02	$0.06	$0.11	Ref. 2
(8) Total Cost of Printing Page	$0.03	$0.09	$0.15	Row 6 + Row 7
(9) Annual Printing Cost Savings	**$941,472**	**$2,671,020**	**$4,400,569**	Row 5 * Row 8

3. eCopy Media Cost Savings

In Table 8 we estimate the eCopy media cost savings of the proposed rule. By reducing the number of eCopies needed for some types of submissions, the proposed rule would produce additional eCopy cost savings related to purchasing eCopy media. The least expensive type of eCopy media is a CD, which costs on average $0.26 per CD. DVDs cost $0.49 per unit on average and flash drives cost an average of $2.56 per unit. If we assume that eCopies are one-third CDs, one-third DVDs, and one-third flash drives, the average cost per eCopy is $1.10.

Firms must currently submit more than one eCopy for some types of PMAs (including original PMAs) and for eligible IDEs. As shown in Table 6, the proposed rule would decrease the number of eCopies required for each IDE from 2 eCopies to 1 eCopy. The proposed rule would decrease the average number of eCopies required per PMA by between 0 and 4 eCopies, with a primary estimate of 1.78 eCopies.[1] Therefore, the total annual reduction in the number of

[1] The number of PMA eCopies submitted to FDA depends on the type of PMA submission. Some submissions, like Annual Reports and Post-Approval Study Reports, require only a single eCopy, and the proposed rule would not change their submission requirements. Other submissions, like original PMAs, Panel-Track Supplements, and 180-Day Supplements, require 5 eCopies. If FDA receives only Annual Reports and Post-Approval Study Reports each year, then the average reduction in the number of eCopies required per PMA would be 0 eCopies. If FDA receives

eCopies created for submission to FDA would range from 15,000 to 35,000 eCopies, with a primary estimate of 23,889 eCopies.

The total annual eCopy media cost savings equals the cost per eCopy times the annual reduction in the number of eCopies submitted under the proposed rule. The eCopy cost savings would range from $3,840 to $89,601 annually, with a primary estimate of $26,338 annually.

Table 8. Annual eCopy Media Cost Savings of the Proposed Rule

Value	Low Estimate	Primary Estimate	High Estimate	Source
(1) Cost of eCopy Media	$0.26	$1.10	$2.56	Assumption
(2) Annual IDEs Submitted	15,000	15,000	15,000	Table 4
(3) Reduction in Number of IDE eCopies per Submission	1	1	1	Table 6
(4) Total Annual Reduction in Number of IDE eCopies	15,000	15,000	15,000	Row 2 * Row 3
(5) Annual PMAs Submitted	5,000	5,000	5,000	Table 4
(6) Reduction in Number of PMA eCopies per Submission	0.00	1.78	4.00	Table 6
(7) Total Annual Reduction in Number of PMA eCopies	0	8,889	20,000	Row 5 * Row 6
(8) Total Annual Reduction in Number of eCopies	15,000	23,889	35,000	Row 4 + Row 7
(9) Annual eCopy Media Cost Savings	**$3,840**	**$26,338**	**$89,601**	**Row 1 * Row 8**

4. Shipping Cost Savings

In Table 9 we estimate the shipping cost savings of the proposed rule. The proposed rule would reduce the shipping cost by decreasing the size and weight of submission shipments to FDA. Based on baseline practices by industry and the recommendations of the eCopy guidance, we assume that firms ship all submissions using priority, flat-rate mail.

We obtain data on shipping costs using information from FedEx and the USPS websites.[2] The majority of sponsors ship submissions to FDA using FedEx. We assume that baseline submissions fit in a large box. Given this assumption, the baseline shipping cost per submission ranges from $18.59, using the flat-rate USPS shipping cost, to $42.50, using the national, flat-rate FedEx shipping cost. The average cost of shipping a baseline submission is $30.54. We assume that submissions under the proposed rule are sent in the lowest cost flat-rate priority shipping. Given this assumption, the new shipping cost per submission ranges from $6.41, using

only original PMAs, Panel-Track Supplements, or 180-Day Supplements in a year, then the average reduction in the number of eCopies required per PMA would be 4 eCopies. If FDA receives equal numbers of all types of PMAs in a year, then the average reduction in the number of eCopies required per PMA would be 1.78 eCopies.

[2] We collected shipping cost data in October 2017 and adjusted to 2016 dollars using the second quarter GDP price index for 2017 and the annual GDP price index for 2016.

the flat-rate USPS shipping cost, to $9.75, using the national, flat-rate FedEx shipping cost. The average cost of shipping a new submission is $8.08. The proposed rule would reduce the shipping cost per submission by between $12.18 and $32.75, with a primary estimate of $22.46.

The total annual shipping cost savings equals the reduction in the shipping cost per submission times the annual number of submissions. The shipping cost savings range from $0.37 million to $0.98 million annually, with a primary estimate of $0.68 million annually.

Table 9. Annual Shipping Cost Savings of the Proposed Rule

Value	Low Estimate	Primary Estimate	High Estimate	Source
(1) Total Annual Submissions	30,050	30,050	30,050	Assumption
(2) Baseline Shipping Cost per Submission	$18.59	$30.54	$42.50	Assumption
(3) New Shipping Cost per Submission	$6.41	$8.08	$9.75	Assumption
(4) Reduction in Shipping Cost per Submission	$12.18	$22.46	$32.75	Row 2 - Row 3
(5) Annual Shipping Cost Savings	**365,910**	**675,024**	**984,138**	**Row 1 * Row 4**

5. Total Cost Savings of the Proposed Rule

In total, the proposed rule would save firms between around $1.31 million and $5.48 million dollars in shipping, printing, and eCopy costs annually (Table 10). The rule would achieve these costs savings by reducing the amount of paper required for some types of submissions and by removing the duplicate eCopy submission requirements. Over 10 years, the present value of the total cost savings is between $11.52 million and $48.10 million at a 3 percent discount rate and between $9.85 million and $41.14 million at a 7 percent discount rate.

Table 10. Summary of Cost Savings ($ millions)

Value	Low Estimate	Primary Estimate	High Estimate
Annual Cost Savings	$1.31	$3.38	$5.48
Present Value of Cost Savings over 10 Years (3 percent)	$11.52	$29.63	$48.10
Present Value of Cost Savings over 10 Years (7 percent)	$9.85	$25.34	$41.14

E. Costs of the Proposed Rule

Firms that plan to submit any of the above submission types in the future would incur one-time costs to read and understand the proposed rule, and one-time costs to change their standards of practice. Assuming an average reading speed of 200 words per minute, we estimate that general management at existing firms would require approximately 0.5 hours to read and understand the rule and 1.5 hours to change standards of practice. An update of the eCopy

guidance published with the proposed rule helps keep the time needed to understand the rule to a minimum. Because FDA already requires at least one eCopy for the submission types affected by the rule, there are no incremental training costs for producing eCopies to existing firms. From the Bureau of Labor Statistics' 2016 National Industry-Specific Occupational Employment and Wage Estimates, the median hourly wage rate for a manager in the medical equipment and supplies manufacturing industry is $59.47. Assuming benefits equal 100 percent of hourly wages, the median cost of an hour of labor is $118.94. The one-time incremental administrative cost per firm would be $237.88 (2 hours × $118.94).

According to our registration data, 21,052 firms registered as medical device establishment owners in 2015. We assume that all medical device firms would immediately change their standards of practice to reflect the new submission requirements. Given this assumption, the total one-time administrative cost of the rule will be $5,007,850 ($237.88 × 21,052 firms). This value likely overestimates the cost of the rule. Firms may not read the rule and change their standards of practice until they prepare a new submission. Not all firms prepare a new submission each year. In this case, fewer firms would incur the one-time administrative fee, and those firms that would change their standards of practice may stagger their response to the proposed rule.

F. Net Benefits of the Proposed Rule

Table 11 presents the present value and annualized value over 10 years of the proposed rule's total benefits, total costs, and net benefits. The printing, shipping, and eCopy savings accrued by firms are larger than the administrative costs of the rule, resulting is positive net benefits. Over 10 years, at a 3 percent discount rate, the proposed rule would result in net benefits of between $6.51 and $43.09 million, with annualized net benefits of between $0.74 and $4.90 million. Over 10 years, at a 7 percent discount rate, the proposed rule would result in net benefits between $4.85 million and $36.13 million, with annualized net benefits of between $0.64 million and $4.81 million.

Table 11. Benefits, Costs, and Net Benefits of the Proposed Rule over 10 Years ($ millions)

Value	Low Estimate (3%)	Primary Estimate (3%)	High Estimate (3%)	Low Estimate (7%)	Primary Estimate (7%)	High Estimate (7%)
Present Value of Total Benefits	$11.52	$29.63	$48.10	$9.85	$25.34	$41.14
Present Value of Total Costs	$5.01	$5.01	$5.01	$5.01	$5.01	$5.01
Present Value of Net Benefits	**$6.51**	**$24.62**	**$43.09**	**$4.85**	**$20.34**	**$36.13**
Annualized Value of Total Benefits	$1.31	$3.37	$5.47	$1.31	$3.37	$5.47
Annualized Value of Total Costs	$0.57	$0.57	$0.57	$0.67	$0.67	$0.67

Annualized Value of Net Benefits	**$0.74**	**$2.80**	**$4.90**	**$0.64**	**$2.71**	**$4.81**

III. Initial Regulatory Impact Analysis

FDA has examined the economic implications of the proposed rule as required by the Regulatory Flexibility Act. If a rule would have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. While small firms make up most the medical device industry, the proposed rule, if finalized, would not have a significant economic impact on these firms. Some firms would incur administrative costs from the rule but would not benefit from the rule's cost-savings if they do not submit a new PMA, 510(k) or IDE. The total one-time cost to such firms will be $237.88, which represents a small fraction of the average annual revenue of medical device firms. This analysis, together with other relevant sections of this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

IV. References

1. U.S. Food and Drug Administration, "eCopy Program for Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff," available at http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm313794.pdf, October 10, 2013.
2. Quality Logic, "Cost of Ink Per Page Analysis, United States," available at https://www.qualitylogic.com/wp-content/uploads/2016/07/QualityLogic-Cost-of-Ink-Per-Page-Analysis_US_1-Jun-2012.pdf, June 2012.